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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,277	05/14/2001	Nathan Lewis	18564001921	2894

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EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 04/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/855,277

Applicant(s)
Lewis et al.

Examiner
Dwayne K. Handy

Art Unit
1743



-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 14-31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 14-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-9 and 14-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,319,724 (Lewis et al.) in view of Lewis et al. (U.S. Pat. No. 6,244,096). Lewis ('741) claims a method for detecting pneumonia, comprising the steps of contacting an array of sensors with breath suspected of containing a marker gas indicative of pneumonia and then detecting the marker gas to determine the presence of pneumonia. Lewis then claims sensor arrays (cl. 2) which may be used in the method, the gases which may be detected as marker gases (cl. 3) and the use of a neural net for gas comparison. Lewis ('096) teaches a sensor based fluid detection device. The device in Lewis ('096) contains the same mechanical elements as the sensor array disclosed in Lewis ('741'). Lewis ('096), in teaching the many uses of their sensor array, teach medical applications in column 8-10. Lewis ('096) claims a device for detecting a microorganism marker gas (cl. 1), then claims the marker gas is indicative of a medical condition, infection, or illness

(cl. 29). Finally, Lewis ('096) claims that the medical condition is member of the group including "...an oral infection, pneumonia, vaginitis, fertility....". Also, throughout columns 8-10, Lewis ('096) recites the various marker gases required for the determination of these conditions. It would have been obvious to one of ordinary skill in the art to combine the teachings of Lewis ('096) with Lewis ('741) to obtain a method(s) as claimed by applicant in claims 1-9 and 14-23. Lewis ('741) teaches pneumonia detection through marker gas detection. Lewis ('096), in claims 29-31, claims that the device - contained in both disclosures and claims - may be used to detect the conditions described in the instant claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 1-4, 24, 26, 27, 29, and 30 rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al. (6,170,318). Lewis teaches methods for using fluid detection devices. The methods include detection of a wide variety of compounds by resistively sensing the presence of the analyte compound in a fluid (col. 12, lines 6-37). Lewis teaches a preferred embodiment of the sensor in the Examples and lists compounds for use in the device in column 8. The sensor includes a chemiresistor and detection equipment. In column 18, Lewis teaches the use of the fluid detection device for detecting halitosis: "Halitosis in particular is a common hygiene

problem that is not readily self detectable. A sensor-based odor detection comprised of a sensor, a fluid delivery device, an electronic measuring device, and an information storage and processing device can detect the presence of human breath vapors. Neural network software attached to the sensor array can compare the human breath vapors with a library of bad breath smells and provide a response to indicate the presence of unpleasant odors.” The Examiner submits that this recitation along with the cited teachings on the elements of the device meet the limitations of the rejected claims. The reference teaches contacting the sensor array with breath, detecting analytes within the breath, and then comparing the found analytes with a library of bad smells to determine the presence of halitosis. The comparison teaching also meets the limitations of new claims 24, 26, 27, 29, and 30.

5. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Rounbehler et al. (6,057,162). Rounbehler teaches disease diagnosis by determination of sulfur compounds in a vapor sample. The vapor sample is delivered through a mouthpiece and hose directly to a detector unit or to a trap that collects the sample for later release. The detection unit includes a gas chromatograph and a chemiluminescence detector (col. 3, line 30-50). Rounbehler teaches that sulfur compound detection may be used to diagnose the presence of cancer or precancer, liver disease, internal infections, ulcers, bacterial infections, viral infections or heart disease (col. 2, lines 21-25). The reference also teaches that “The breath analyzer in certain embodiments can be used to detect infections, or it can be used to detect and determine the origin of bad breath in a patient.” (col. 7, lines 61-63).

Inventorship

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or

nonobviousness.

9. Claims 25 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (6,170,318). Lewis, as described in paragraph 4 above, teaches every element of claims 25 and 31 except for the formation of a breath database by repetitive sampling. It would be obvious to one of ordinary skill in the art, however, to compile a library of known breath samples by sampling multiple breaths.

10. Claim 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Rounbehler et al. in view of Payne et al. (WO 95/33848). Rounbehler, as described above in paragraph 5, teaches every element of claim 4 except for the use of a neural net trained against marker gases of known bacteria. Payne et al. also teach a method for detecting bacteria through marker gas analysis (claims 1-6). The method of Payne includes comparing the sensor response to a neural net. It would have been obvious to one of ordinary skill in the art to combine the use of a neural net with the method of Rounbehler. Using a neural net would allow for the comparison of many more gas indicators against previously loaded library files. This would enhance the diagnosis capabilities of the method.

11. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rounbehler et al. in view of applicant's admission of prior art references. Rounbehler teaches that volatile sulfur compound detection may be used to diagnose the presence of cancer or precancer, liver disease, internal infections, ulcers, bacterial infections, viral infections or heart disease (col. 2, lines 21-25). Rounbehler also recites bad breath detection (col. 7, line 63). Rounbehler does not

specifically recite periodontal disease diagnosis. In the specifications of the instant application, applicant has cited several references from available literature which disclose the chemical markers of periodontal disease which include volatile sulfur compounds (page 13, lines 20-25). It would have been obvious to one of ordinary skill in the art to modify the method of Rounbehler to diagnose periodontal disease based on the teachings of Rounbehler and the disclosure from any of these cited references that volatile sulfur compounds are indicators of periodontal disease. Rounbehler already teaches bacterial infection diagnosis along with assessing bad breath - a condition of the mouth - through analysis of sulfur compounds. It would be obvious to also diagnose periodontal disease while assessing conditions in the mouth since bacterial infection is a known cause of periodontal disease.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rounbehler et al. in view of applicant's admission of prior art references and further in view of Payne et al. (WO 95/33848). Rounbehler and the admitted prior art, as described above in paragraph 11, combine to teach every element of claim 4 except for the use of a neural net trained against marker gases of known bacteria. Payne et al. also teach a method for detecting bacteria through marker gas analysis (claims 1-6). The method of Payne includes comparing the sensor response to a neural net. It would have been obvious to one of ordinary skill in the art to combine the use of a neural net with the method of Rounbehler. Using a neural net would allow for the comparison of many more gas indicators against previously loaded library files. This would enhance the diagnostic capabilities of the method.

13. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al

(patent number 5,571,401) in view of Cutler et al. Lewis et al. discloses a general method for using an array of sensors (chemiresistors) to detect the presence of an analyte. The method is put forth in column 8, lines 6-17, and column 7, lines 23-58. Lewis et al. also states that their chemiresistor sensors can be used to detect "broad ranges of chemical classes such as organics such as alkanes, alkenes, alkynes, dienes, alicyclic hydrocarbons, arenes, alcohols, ethers, ketones aldehydes, carbonyls, carbanions, polynuclear aromatics and derivatives of such organics,....biomolecules such as sugars, isoprenes and isoprenoids, fatty acids, and derivatives,etc." Finally, Lewis states that commercial applications of the sensors includes biomedicine. Cutler et al. discloses a method for determining the onset of the fertile period of a human female by monitoring the compounds androstenol and/or dehydroepiandrosterone. This method can be used to predict the occurrence of ovulation (see the Cutler Abstract). It would have been obvious to one of ordinary skill in the art to use the sensor array as claimed by Lewis in a method for detecting the compounds that indicate ovulation (remember that Lewis et al. also put forth a method for determining analyte gases). Since Lewis et al. suggested that their sensor could be used in biomedical applications, one would wish to use their apparatus and method to detect gases that are indicative of a medical condition.

14. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (patent number 5,571,401) in view of the applicant's admission of prior art. Lewis et al. discloses a general method for using an array of sensors (chemiresistors) to detect the presence of an analyte. The method is put forth in column 8, lines 6-17, and column 7, lines 23-58. Lewis et al. also states that their chemiresistor sensors can be used to detect "broad ranges of chemical classes such as organics such as alkanes, alkenes, alkynes, dienes, alicyclic hydrocarbons, arenes,

hydrocarbons, arenes, alcohols, ethers, ketones, aldehydes, carbonyls, carbanions, polynuclear aromatics and derivatives of such organics,....biomolecules such as sugars, isoprenes and isoprenoids, fatty acids, and derivatives, etc.” Finally, Lewis states that commercial applications of the sensors includes biomedicine.

In the specifications of the current application, the applicant has admitted prior art as citations of which marker gases may be present in the case of vaginitis infection (page 15, lines 15-17). The applicant cites several references which list the marker compounds for each condition. Since many of these well known marker gases are included in the list put forth by Lewis et al. in their patent, and Lewis et al. suggests that their sensor array can be used in biomedicine, it would have been obvious to one of ordinary skill in the art to use the sensor array as disclosed by Lewis et al. to detect a medical condition by detecting the marker gas(es) which correspond(s) to the condition. Thus claims 14-17 are rejected.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bolbot et al. (WO 94/04916) recites a method and apparatus for detecting volatile amines from a swab sample. The presence of volatile amines is indicative of vaginosis.


Lemelson (5,787,885) shows a body fluid analysis system which may act as a portable testing system for breath and other fluids. Phillips (5,848,975) and Katzman (6,067,989) both teach a method for diagnosing *Helicobacter pylori* infections through detection of labeled species in breath samples.

16. Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

March 23, 2002